CLAIMS

What is claimed is:

1. A construct capable of infecting a mammalian cell comprising at least one semi-purified or pure SV40 capsid protein; and a constituent selected from the group consisting of:

a) an exogenous DNA encoding a therapeutic exogenous protein or peptide product, or encoding therapeutic RNA, or itself a therapeutic product,

b) a vector comprising an exogenous DNA encoding a therapeutic exogenous protein or peptide product, or encoding therapeutic RNA, or itself a therapeutic product,

c) an exogenous RNA encoding a therapeutic exogenous protein of peptide product or itself a therapeutic product,

d) vector comprising an exogenous RNA encoding a therapeutic exogenous protein or peptide product or itself a therapeutic product,

e) therapeutic exogenous protein or peptide product, and

f) antisense RNA, ribozyme RNA or any RNA or DNA which inhibits or prevents the expression of undesired protein or proteins in said mammalian cell; and further comprising operatively linked regulatory elements sufficient for the expression

and/or replication of said exogenous protein in a mammalian cell.

2. A construct according to Claim 1 further comprising additional SV40 protein or proteins, preferably SV40 agnoprotein.

3. A construct according to Claim 1 comprising a mixture of at least two semi-purified or pure SV40 capsid proteins.

4. A construct according to Claim 1 comprising a mixture of three semi-purified or pure SV40 capsid proteins.

5. A construct according to Claim 1 wherein said SV40 capsid protein is semi-purified or pure VP1 or VP2 or VP3.

6. A construct according to Claim 1 wherein said constituent is exogenous circular or linear DNA encoding a therapeutic exogenous protein or peptide product, or itself a therapeutic product, or encoding therapeutic RNA, or a vector comprising exogenous DNA encoding therapeutic RNA or encoding a therapeutic exogenous protein or peptide product.

7. A construct according to Claim 6 wherein said DNA is DNA which encodes a therapeutic protein or peptide product which is not made or contained in said cell, or is DNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in abnormally low amount, or is DNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in defective form or is DNA

which encodes a therapeutic protein or peptide product which is made or contained in said cell in physiologically abnormal or normal amount, or encodes a therapeutic RNA.

8. A construct according to Claim 7 wherein said therapeutic protein or peptide product is an enzyme, a receptor, a structural protein, a regulatory protein or a hormone.

9. A construct according to Claim 1 comprising SV40-derived *ori* DNA sequence as a replication regulatory element and further comprising a DNA sequence encoding one or more regulatory elements sufficient for the expression of said exogenous RNA or exogenous protein or peptide in said mammalian cell.

10. A construct according to Claim 1 wherein said constituent is exogenous RNA, wherein said RNA is RNA which encodes a therapeutic protein or peptide product which is not made or contained in said cell, or is RNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in abnormally low amount, or is RNA which encodes a therapeutic protein or peptide product which is made contained in said cell in defective form, or is RNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in physiologically abnormal or normal amount, said RNA having regulatory elements, including translation signal or signals sufficient for the translation of said protein or peptide product in said mammalian cell, operatively linked thereto.

11. A construct according to Claim 10 wherein said therapeutic protein or peptide product is an enzyme, a receptor, a structural protein, a regulatory protein or a hormone.

12. A construct according to Claim 1 wherein said constituent is a therapeutic exogenous protein or peptide product which is, respectively, a therapeutic protein or peptide product which is not made or contained in said cell, or is a therapeutic protein or peptide product which is made or contained in said cell in abnormally low amount, or is a therapeutic protein or peptide product which is made or contained in said cell in defective form or is a therapeutic protein or peptide product which is made or contained in said cell in physiologically abnormal or normal amount.

13. A construct according to Claim 1 wherein said constituent is antisense RNA or DNA or ribozyme RNA. or any RNA or DNA which inhibits or prevents the expression of undesired protein or proteins in said mammalian cell.

14. A construct according to Claim 13 wherein said antisense RNA is antisense RNA directed against the *bcr/abl* transcript.

15. A construct according to Claim 13 wherein said antisense RNA is antisense RNA directed against a HIV transcript.

16. A construct according to Claim 1 wherein said cell is a human cell selected from the group consisting of

hemopoietic cells, epithelial cells, endothelial cells, liver cells, epidermal cells, muscle cells. tumor cells, nerve cells and germ line cells.

17. A construct according to Claim 16 wherein said hemopoietic cells are bone marrow cells, peripheral blood cells and cord blood cells, or liver cells.

18. A method for the *in vitro* construction of SV40 viruses or pseudoviruses comprising exogenous nucleic acid comprising the following steps:

a. allowing a semi-purified or pure SV40 capsid protein or a mixture of at least two such proteins to self-assemble into SV40-like particles; and

b. bringing the SV40-like particles assembled in step (a) into contact with said exogenous nucleic acid to give recombinant SV40 viruses or with a vector comprising said exogenous nucleic acid to give pseudoviruses.

19. The method of Claim 18 wherein said recombinant SV40 viruses or pseudoviruses are subjected to digestion by nuclease to remove non-packaged DNA.

20. A method according to Claim 18 wherein in step (a) at least one other SV40 protein, preferably SV40 agnoprotein, is added to the mixture of said SV40 capsid protein or proteins and said nucleic acid.

21. A method according to Claim 18 wherein said SV40 capsid protein is semi-purified or pure SV40 VP1, VP2, or VP3.

22. A method according to Claim 18 wherein said exogenous nucleic acid is circular or linear DNA.

23. A method according to Claim 18 wherein said exogenous nucleic acid is RNA.

24. A method according to Claim 18 wherein said exogenous nucleic acid encodes a therapeutic protein or peptide product or itself a therapeutic product.

25. A method according to Claim 22 wherein said DNA is DNA which encodes a therapeutic protein or peptide product which is not made or contained in said cell, or is DNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in abnormally low amount, or is DNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in defective form or is DNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in physiologically abnormal or normal amount or is DNA which encodes a therapeutic RNA.

26. A method according to Claim 25 wherein said exogenous DNA encodes a therapeutic protein or peptide product which is an enzyme, a receptor, a structural protein, a regulatory protein or a hormone.

27. A method according to Claim 18 wherein in step (b) SV40-derived *ori* DNA sequence is added and said

exogenous nucleic acid has DNA sequence encoding one or more regulatory elements sufficient for the expression of said exogenous protein in said mammalian cell operatively linked thereto.

28. A method according to Claim 18 wherein said nucleic acid is exogenous RNA, wherein said RNA is RNA which encodes a therapeutic protein or peptide product which is not made or contained in said cell, or is RNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in abnormally low amount, or is RNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in defective form or is RNA which encodes a therapeutic protein or peptide product which is made or contained in said cell in physiologically abnormal or normal amount and wherein said RNA has regulatory elements, including translation signal, sufficient for the translation of said protein product in said mammalian cell, operatively linked thereto.

Sub B5 cont.

29. A method for the *in vitro* construction of recombinant SV40 viruses or pseudoviruses comprising an exogenous therapeutic protein or peptide comprising the following steps:

a. allowing a semi-purified or purified SV40 capsid protein or a mixture of at least two such proteins to self-assemble into SV40-like particles; and

b. bringing the SV40-like particles assembled in step (a) into contact with said exogenous protein

to give recombinant SV40 viruses or pseudoviruses.

30. A method according to Claim 29 wherein said recombinant SV40 viruses or pseudoviruses are purified from any non-packaged protein.

31. A method according to Claim 29 wherein said exogenous protein or peptide are, respectively, a naturally occurring or recombinant protein or peptide, a chemically modified protein or peptide, or a synthetic protein or peptide.

32. A method according to Claim 31 wherein said exogenous protein or peptide product is, respectively, a therapeutic protein or peptide product not made or contained in said cell, or are a therapeutic protein or peptide product made or contained in said cell in abnormally low amount, or are a therapeutic protein or peptide product made or contained in said cell in defective form or are a therapeutic protein or peptide product made or contained in said cell in physiologically abnormal or normal amount.

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33. A method according to Claim 32 wherein said cell is a human cell selected from the group consisting of hemopoietic, cells, muscle cells, tumor cells, nerve cells and germ line cells.

34. A method according to Claim 33 wherein said hemopoietic cells are bone marrow cells, peripheral blood cells and cord blood cells, or liver cells.

35. A method for the *in vitro* construction of SV40 pseudoviruses comprising exogenous antisense RNA, or ribozyme RNA or RNA or DNA which inhibits or prevents the expression of undesired protein or proteins in a mammalian cell, comprising the following steps:

a. allowing a semi-purified or pure SV40 capsid protein or a mixture of at least two such proteins to self assemble into SV40-like particles and

b. bringing said SV40-like particles obtained, in step (a) into contact with said exogenous antisense RNA, or ribozyme RNA, or RNA or DNA which inhibits or prevents the expression of undesired protein/s in a mammalian cell, to give recombinant SV40 pseudoviruses.

36. The method of Claim 35 wherein said pseudoviruses are subjected to digestion by nuclease to remove non-packaged DNA.

37. A method according to Claim 35 wherein in step (a) at least one other SV40 protein, preferably SV40 agnoprotein, is added to the mixture of SV40 capsid protein or proteins and the exogenous nucleic acid or antisense nucleic acid.

38. A method according to Claim 35 wherein said SV40 capsid protein is semi-purified or pure SV40 VP1, VP2, or VP3.

39. A method according to Claim 35 wherein said antisense RNA is antisense RNA directed against the *bcr/abl* transcript.

40. A method according to Claim 35 wherein said antisense RNA is antisense RNA directed against a HIV transcript.

41. A mammalian cell infected with a construct of Claim 1.

42. An infected human cell according to Claim 41 selected from the group consisting of hemapoietic cells, muscle cells, tumor cells, nerve cells and germ line cells.

43. A method of providing a therapeutic DNA, RNA, antisense RNA, ribozyme RNA, protein or peptide product to a patient in need of such product by administering to said patient a therapeutically effective amount of the SV40 viruses or pseudoviruses according to Claim 1.

44. A method of providing a therapeutic, DNA, RNA, antisense RNA. ribozyme RNA, protein or peptide product to a patient in need of such product by administering to said patient a therapeutically effective amount of infected cells according to Claim 41.

45. Pharmaceutical compositions comprising as active ingredient a therapeutically effective amount of the SV40 viruses or pseudoviruses according to Claim 1.

Sub B7 cont

46. Pharmaceutical compositions comprising as active ingredient a therapeutically effective amount of infected cells according to Claim 41.

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